

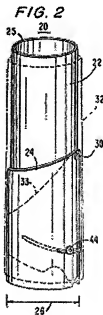
REMARKS

Prior to this amendment, Claims 1-27 were pending in this application. New Claims 28-32 have been added. Accordingly, Claims 1-32 remain pending. Additionally, Claims 26 and 27 have been amended to correct inadvertent typographical errors.

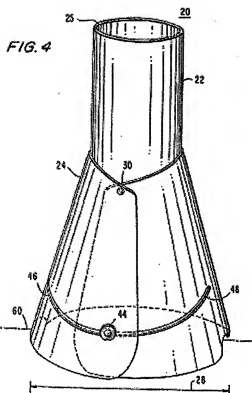
Discussion of a Preferred Embodiment

Broadly, this application is directed to methods of treating a patient's spine. More particularly, in one embodiment, this application discloses a method of accessing the spine and coupling implants therewith.

Figures 2 (reproduced below) and 15 illustrate a method step wherein an access device is inserted into the body of the patient. One example of an access device is a cannula 20 illustrated in Figure 2.



The access devices usable in the methods disclosed in certain embodiments of this application can include an elongate body that has a proximal and distal end, an outer surface, and an inner surface. The inner surface can define an access path that extends through the elongate body through which surgical instruments, implants and fasteners can be inserted to a surgical location proximate the spine. More details on one such access device are shown in Figure 4 (reproduced below).

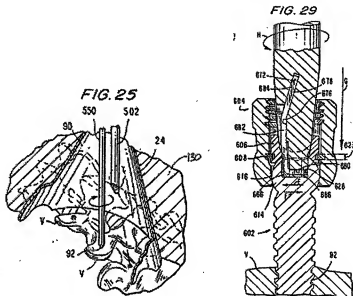


The access device of Figures 2 and 4 is an example of an access device that can be used in the methods disclosed in certain embodiments of this application. As shown in Figure 2, the access device can have a first or reduced configuration having a first cross-sectional area (or first transverse dimension) adapted for insertion through an incision on the patient's skin. The access device can be inserted in a variety of approaches to reach a desired spinal location, including an anterior approach and a generally posterior approach. Once the access device has been advanced to the desired spinal location, the access device can be expanded, as shown for example in Figure 4, to a second configuration having an enlarged cross-sectional area (or second transverse dimension greater than the first transverse dimension).

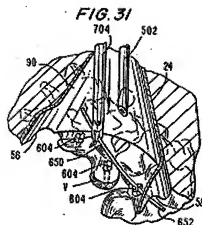
In one embodiment disclosed in the present application, after access to the spinal location has been provided through the access device, an implant, such as a fusion device, can be moved through the access device to the surgical location and coupled with a vertebra. The fusion device can be, for example a fusion cage or a femoral ring.

In another technique, multiple implants can be moved through the access device to the spinal location. For example, a first fastener and a second fastener can be coupled with two adjacent vertebrae. The fasteners can be similar to the fastener 600 and can be conventional

pedicle screws. The first fastener can be moved through the access device 20 and secured to the first vertebra V and a second fastener can be moved through the access device 20 and secured to the second vertebra V. In connection with illustrating an optional step of preparing a pedicle to receive a fastener, Figure 25 (reproduced below) shows that the access device 20 can be used to expose multiple pedicles such that the first and second fasteners can be inserted into the pedicles without removing and reinserting the access device 20. Figure 29 shows how one of the first and second fasteners can be coupled with one of the vertebrae.

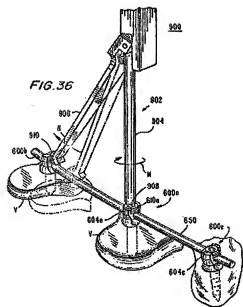


If two fasteners are coupled with adjacent vertebrae, additional optional steps related to coupling an elongated member with the fasteners can be performed. One such elongated member can be, for example, the fixation element 650 or other member that spans between at least two fasteners coupled to pedicles on adjacent vertebrae. Some such additional steps are illustrated in part in Figure 31 (reproduced below).



As shown above, the fixation element 650 can be moved through the access device 20 and can be coupled with the housing 604 of adjacent fasteners 600. As discussed above, Figures 25 and 31 illustrate the amount of space that can be provided according to some of the techniques disclosed and claimed in this application, by providing, in some techniques, a distally expanding structure wherein a workspace defined at a distal end of the access device is enlarged to provide access to two or more adjacent pedicles.

In another technique, implants, such as the fastener 600, can be moved through the access device to the spinal location and coupled to three adjacent vertebrae. For example, a first fastener 600a, a second fastener 600b, and a third fastener 600c, can be inserted through an access device and coupled to a first vertebra V, a second vertebra V adjacent to the first vertebra, and a third vertebra adjacent to the second vertebra, respectively. Figure 36 shows how the fasteners 600a-600c can be coupled to the three adjacent vertebrae.



The present application further discloses, in some embodiments, performing multiple procedures on a patient's spine, at least some of which would be performed through the access device. For example, a variety of procedures, such as a multilevel fixation procedure (e.g., a two-level or three-level procedure), a decompression procedure and/or delivery of bone growth material may be conducted generally posteriorly and combined with an anterior lumbar interbody fusion (ALIF) procedure. A fusion implant, such as a fusion cage or a femoral ring may be used in the ALIF procedure. Also, the decompression procedure may include a laminectomy, a facetectomy or any suitable procedure for removal of bone. Such procedures can include performing the ALIF procedure and then inserting the access device generally posteriorly on the patient's spine and expanding the access device to expose at least a portion of three adjacent vertebrae. The multilevel fixation procedure, decompression procedure and/or delivery of bone growth material can then be performed via the expanded access device.

Other embodiments disclosed in the present application contemplate performing a posterior minimally invasive lumbar interbody fusion (MILIF) in combination with a multilevel fixation procedure, a decompression procedure and/or delivery of bone growth material through the access device.

Obviousness Rejection

Claims 1-20, 22-25 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over various combinations of Foley et al. (U.S. Patent No. 5,792,044), Davison (U.S. Patent No. 6,187,000), Matthews (U.S. Patent No. 6,793,656), Justis (U.S. Patent No. 6,293,949), and Chan (U.S. Patent No. 6,626,909).

Foley et al.

The Examiner asserts that Column 9, lines 63-67 and Column 10, lines 1-11 of Foley teach “a method of treating the spine that is applicable to a wide range of surgical procedures in any region of the body via any approach.” Office Action, page 2, paragraph 3. The Examiner also asserts that Column 15, lines 35-67, and Column 16, lines 1-9 of Foley teaches “a method comprising the steps of implanting a fusion device in the space between at least two vertebrae and inserting an access device into the patient,” and that “fusion and fixation methods can be performed through the access device.” Id. Applicants respectfully disagree with the Examiner’s assertion and respectfully submit that Foley fails to teach or suggest the specific combination of steps recited by each of Applicants’ claims. Moreover, as discussed further below, Foley is not combinable with the other references, and could not properly be modified, as cited by the Examiner in the rejections of the claims.

Foley is directed to a device 10 (Figure 1, reproduced below) for percutaneous surgery that includes an elongated cannula 20 having a first inner diameter D_1 and an outer diameter D_o , sized for percutaneous introduction into a patient. The cannula 20 also includes a distal working end 21 and an opposite proximal end 22. The cannula 20 defines a working channel 25 between the ends 21, 22 having a second diameter d_2 equal to the first inner diameter D_1 and sized for receiving a tool therethrough.

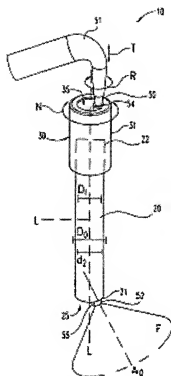


Fig. 1

The cannula 20 is configured to be inserted over a dilator. This step is illustrated in Figure 10e. See Foley, Col. 10 at lines 35-59.



Fig. 10e

The cannula 20 is described as having a “maximum diameter d_2 ” of 12.7 mm, with the effective working space being only about 8 mm due to the presence of a viewing element 50. See Foley, Col. 12 at lines 29-35. Although Foley says that his invention “is not limited to particular sizes for the working channel” (Column 12, line 36), there is no suggestion to make the Foley

cannula large enough to make the diameter d_2 large enough to permit passage of multiple fasteners therethrough to perform procedures discussed in certain embodiments of the present application, which are disclosed as being performed by accessing two or more adjacent vertebrae through a single device that is capable of simultaneously exposing the two or more adjacent vertebrae.

Most of the procedures disclosed by Foley are performed at a single site (a single disc space or a portion of one vertebra, such as a single pedicle or lamina of a vertebra). See e.g., Column 13, lines 48-54; column 15, lines 44-48; Figures 10e-10i. Though Foley states at Column 4, lines 12-15 that "all steps of a surgical procedure are conducted under direct vision through a single working channel cannula," where a procedure is performed over a larger area (e.g., a procedure involving access to pedicles on two or more adjacent vertebrae), Foley teaches removing the cannula 20 and then re-inserting it at another location either up or down the spine. For example, Foley teaches that such procedures are conducted by "sequentially inserting the working channel cannula 20 through *several small cutaneous incisions along the spinal midline*" or by placing several working channel cannulae 20 "*at each of the small cutaneous incisions.*" Foley, Column 13, line 60 – Column 14, line 2 (emphasis added).

Thus, Foley teaches repositioning a relatively small cannula using several small cutaneous incisions when the procedures involve an area that is significantly larger than the size of the cannula's cross-section at its distal end. Though Foley states in Column 12, lines 3-15 that "the cannula can be readily positioned over an appropriate target tissue or bone, to thereby move the working space as necessary for the surgical procedure," there is no suggestion in Foley that such movement of the working space contemplates, for example, exposing two or more adjacent vertebrae. Rather, Foley merely teaches that during a laminotomy such manipulation of the cannula can allow a greater region of bone removal on a single vertebra than defined by the inner diameter of the working channel of the cannula. See Column 13, lines 54-62. Thus, Foley only suggests limited local manipulation of the cannula 20 to access a space that is not significantly larger than that provided by the inner diameter of the working channel. For procedures involving a larger area, e.g., spanning multiple pedicles on two or more adjacent vertebrae, Foley discusses performing such procedures by sequentially inserting the cannula, or inserting multiple cannulae, through multiple small cutaneous incisions, as discussed above.

Foley also teaches away from significantly enlarging the cannula 20. For example, Foley's cannula 20 is made small enough so that the K-wires, which had been used to position screws, are not needed to guide screws into position. Foley states that "the working channel itself can effectively operate as a positioning guide, once the cannula 20 is properly oriented with respect to the vertebra." Column 15, lines 24-26. Foley also teaches that "the location of the bone screw within the vertebra *is critical*, so identification of the position of the cannula 20 over the bony site is necessary." Column 15, lines 15-18. Increasing the size of the working channel to permit passage of *multiple* fasteners would reduce the accuracy of placement considered so critical by Foley. Accurate placement is also fostered, according to Foley, by "centering" his device over "an appropriate target tissue or bone." Column 12, lines 3-9. Unless a much larger area than contemplated by Foley were exposed by his cannula, neither pedicle in a fixation procedure could be considered to be at the center of the projection of Foley's working channel. Also, Foley teaches away from enlarging the cannula 20 to permit passage of multiple fasteners therethrough by teaching that special tools should be used with the cannula. More particularly, rather than increasing the size of the cannula 20 to accommodate more conventional tools, Foley teaches using very special tools that will not obstruct the surgeon's view, e.g., tools with 90° handles, as shown in Figures 4-8 and discussed at Column 12, lines 47-50. Accordingly, Applicants respectfully submit that, contrary to the Examiner's statement on pages 3 and 4 of the Office Action, it would not have been an obvious matter of design choice to make the cannula of Foley be able to extend over at least a portion of three adjacent vertebrae "since such a modification would have involved a mere change in the size of a component." Office Action, page 4, lines 1-3.

Moreover, although Foley refers to fixation as a procedure that can be performed through the cannula 20, apparently by making several incisions on each side of the spine and sequentially inserting and reinserting the cannula 20, Foley contains no teaching for a system for simultaneous delivery of multiple components of a fixation assembly or member through one cannula to fix, or span between fasteners or implants secured to, two or more adjacent vertebrae, let alone how to do so with the sizes and configurations of the cannula 20 disclosed. For example, though Column 15, lines 3-11 in Foley state that "[t]he insertion of vertebral fixation elements can be accomplished through the device 10," Foley does not disclose providing simultaneous access to vertebral locations on two or more adjacent pedicles or other sites on vertebrae where fasteners

can be inserted. Accordingly, the cannula in Foley is not configured for performing therethrough a multi-level procedure across at least three adjacent vertebrae, such as insertion of first, second and third fasteners through the cannula for attachment to three adjacent vertebrae. In contrast, providing access for the insertion of such a fixation assembly and/or fasteners to fix two or more adjacent vertebrae is a feature recited in Applicant's claimed embodiments.

Applicants therefore submit that the cannula of Foley would not be suitable for performing the methods recited in at least Claims 1-32, as Foley provides no teaching or suggestion of, among other things, fasteners or a vertebral fixation assembly being simultaneously inserted through the cannula of Foley to fix said fasteners or vertebral fixation assembly to two or more adjacent vertebrae.

Additionally, though Foley discloses that the cannula 20 can be used for insertion of a fixation element (Column 15, lines 3-18), and that the cannula 10 can be used to prepare a site for fusion of two adjacent vertebrae (Col. 15, lines 35-55), Foley does not teach or suggest performing a combination of procedures, such as an ALIF or MILIF procedure in combination with a multi-level procedure (e.g., a two-level or three-level fixation procedure), a decompression procedure and/or delivery of bone growth material through the access device as part of one surgical intervention, as provided in embodiments described in the present application. Moreover, Foley does not teach or suggest implanting a fusion device via an anterior approach, and performing a multi-level procedure via a generally posterior approach as part of one surgical intervention.

Applicants therefore submit that the cannula of Foley would not be suitable for the methods recited in at least Claims 1-32, as Foley provides no teaching or suggestion to insert or move the structures recited in those claims through its cannula. For example, with respect to Claim 1 and its dependent claims, Foley fails to teach or suggest, among other things, performing a multi-level procedure through the access device across at least three adjacent vertebrae. With respect to Claims 14, 15 and 17 and their dependent claims, Foley fails to teach, among other things, providing a first, second and third fasteners configured for insertion into the patient through the access device and attaching the first, second and third fasteners to a first, second and third vertebrae. With respect to Claim 18 and its dependent claim, Foley fails to teach or suggest, among other things, placing a bone growth substance through the access device and adjacent an interbody space defined between at least two of a first, second and third vertebrae to

enhance bone growth therebetween. With respect to Claim 20, Foley fails to teach or suggest, among other things, actuating an access device to a configuration having an enlarged cross-sectional area at a distal portion thereof that spans at least a portion of a first vertebra, a second vertebra and a third vertebra. With respect to Claim 20 and its dependent claims, Foley fails to teach or suggest, among other things, performing a two-level fixation procedure spanning first and second interbody spaces through the access device.

Davison

The Examiner asserts that Davison teaches "an access device that may be used in a surgical procedure in any region of the body and has a distal end that is capable of being expanded after being inserted into the patient." Office Action, page 3. The Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to "perform the method of Foley with an access device having an expandable distal end in view of Davidson." Id. Applicants respectfully disagree with the Examiner and respectfully submit that there is no motivation to combine Foley with Davidson to provide the claimed invention in the present application, as discussed below.

As discussed above, Foley teaches conducting procedures spanning across areas significantly larger than the cross-sectional area of the cannula (e.g., a procedure involving access to pedicles on adjacent vertebra) by using several small cutaneous incisions along the spinal midline for either sequential insertion of a cannula 20 through the incisions, or insertion of several cannulae 20 through the incisions. Through the use of multiple "small" cutaneous incisions, Foley impliedly teaches the limited retraction of tissue. This teaching is consistent with the dimensions provided in Foley for the cannula (i.e., a maximum diameter d_2 of 12.7 mm). Therefore, Foley effectively teaches away from distal expansion of the cannula, because such expansion would result in increased retraction of tissue. Moreover, if multiple cannulae (modified to incorporate the expandable distal end of Davison) were inserted through the small cutaneous incisions during a multi-level procedure, the cannulae would interfere with each other when their distal ends were expanded, particularly in multi-level procedures where the vertebrae (e.g., cervical vertebrae) are very close together. Further, the use of multiple small cutaneous incisions, which results in limited retraction of tissue, teaches away from the insertion of a single

larger cannula through a larger incision for multi-level procedures, as this would result in increased tissue retraction.

Accordingly, Applicants respectfully submit that there is no motivation to combine Foley and Davison, not only because Foley teaches away from use of a cannula with an expandable distal end, but also because use of such an expandable cannula would result in increased tissue retraction and frustrate the implied teaching in Foley of limited tissue retraction. Additionally, Foley teaches away from using a single cannula for multi-level procedures, as this would require a larger cannula than the one disclosed in Foley and would result, among other things, in increased tissue retraction, again frustrating the implied teaching in Foley of limited tissue retraction. Therefore, Applicants respectfully submit that a prima facie case of obviousness has not been established because there is no motivation to combine Foley and Davison.

Matthews

The Examiner asserts that the combination of Foley and Davison disclose the invention as claimed except for the method steps of performing decompression through the access device prior to performing fixation and providing fasteners through the access device for attaching to vertebrae, attaching the fasteners to vertebrae, inserting an elongated member through the access device, and securing the elongated member to the fasteners, steps that the Examiner assert are taught by Matthews. See Office Action, paragraphs 5 and 8.

Matthews discloses vertebral fixation of adjacent vertebrae with bone screws 30, a fixation plate 40 mounted on the screw 30, and linking members 44 spanning across the midline between the corresponding bone screws 30. See Matthews, Col. 7 at lines 20-30; Figures 1 and 3 (reproduced below).

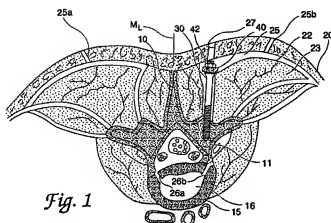


Fig. 1

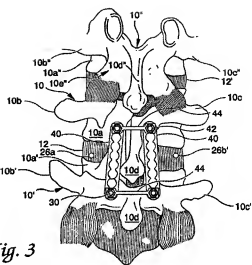


Fig. 3

Matthews also discloses that the bone screws can have a diameter of 5.5-8.5 mm. See Matthews at Column 5, line 67. Additionally, Matthews discloses a set of dilators 50 for insertion of the bone screw into the vertebrae of a patient, wherein the largest dilator (through which the screw is delivered) has a cannulated diameter of 9.58 mm. See Matthews at Column 8, lines 24-60; Figures 4A-4C (reproduced below).

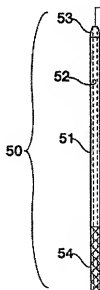


Fig. 4A

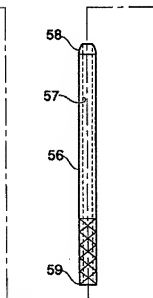


Fig. 4B

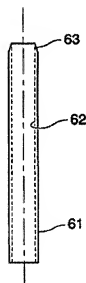


Fig. 4C

That is, even the largest of the dilators in Matthews is just large enough to accommodate delivery of a single bone screw. Accordingly, like Foley, Matthews teaches inserting a tube 61

for each screw to be placed, rather than inserting more than one fastener through a single access device. Column 6, lines 4-6.

Furthermore, although Matthews does teach use of a fixation plate 40, there is no teaching or suggestion in Matthews that the fixation plate 40 is delivered through the largest tube 61. Rather, Matthews describes using pick-ups and Metzenbaum scissors to dissect tissue in order to insert the fixation plate. Column 6, lines 7-13.

Thus, Matthews does not address shortcomings of Foley, discussed above, with respect to at least Claims 14, 15, 17, 20 and their dependent claims. Additionally, Matthews, like Foley, fails to teach actuating an access device to a second configuration having an enlarged cross-sectional area, as recited by Claims 14, 15, 17, 18, 20, 24 and their dependent claims.

Justis

The Examiner asserts that the combination of Foley and Davison disclose the claimed method steps, except for performing a multi-level procedure through the access device across the at least three vertebrae, and that Justis discloses such a step. See Office Action, page 4, paragraph 4. With respect to Claim 14, 15 and 16, the Examiner asserts that Foley, Davison and Matthews disclose the claimed invention except for the step of providing a fastener through the access device for a third vertebrae and attaching the elongated member to a third fastener, and that Justis teaches such a step. See Office Action, page 8, paragraph 9.

Though Justis discloses a stabilization system with an elongate member 22, which can be a spinal rod, Justis does not disclose delivery of such a stabilization system through one access device, as recited in the claimed embodiments, nor does Justis address the shortcomings of Foley, and Matthews, as discussed above. Accordingly, Applicants respectfully submit that the Justis, in combination with Foley and Davison, or further in combination with Matthews fails to establish a prima facie case of obviousness at least with respect to Claims 1, 14, 15, 18, 20, 24 and their dependent claims.

Chin

With respect to Claims 22 and 27, the Examiner asserts that the combination of Foley, Davison, Justis and Matthews discloses the claimed invention, except for the portion of bone removed being from a lamina, and that Chin teaches a method for the fixation and fusing of the spine that includes performing a laminectomy prior to attaching the element of the fixation

system to the vertebrae in order to decompress the vertebrae. See Office Action, page 5, paragraph 6. Though Chin does disclose performing a laminectomy and then placing first, second, third and fourth pedicle screws within the first and second pedicles of the first and second vertebrae, respectively, Chin does not disclose that these steps are performed through an access device, as recited in the claimed embodiments, nor does Chin address the shortcomings of Foley, Matthews and Justis, as discussed above. Accordingly, Applicants respectfully submit that the Chin, in combination with Foley, Davison, Justis and Matthews fails to establish a prima facie case of obviousness at least with respect to Claims 22 and 27.

Summary of Arguments

Applicants respectfully submit that while the five references cited by the Examiner teach devices suited for particular spinal procedures, none of these references, alone or in combination, teaches or suggests the unique combination of steps recited by each of Applicants' claims. As discussed above, Foley does not teach performing a multi-level procedure, such as a two-level or three-level fixation procedure involving the simultaneous delivery of two or more fasteners through an access device to fix two or three adjacent vertebrae. Additionally, Foley does not teach or suggest, for example, implanting a fusion device via an anterior approach and performing a two-level or three-level fixation procedure via a posterior approach as part of one surgical intervention. Further, there is no motivation to combine Davison and Foley because Foley teaches away from using an expandable distal end and because the combination of Foley and Davison would frustrate the teachings in Foley. Further, Matthews also only teaches a cannula that is just large enough to accommodate one fastener therethrough. Justis and Chin also fail to address the shortcomings of Foley and Matthews.

New Claims

New Claims 28 and 29 correspond to Claims 21 and 26, respectively, written in independent form. In accordance with the Examiner's comments that such rewritten claims would be allowable, Applicants respectfully submit that new Claims 28 and 29 are in condition for immediate allowance.

Claims 30 and 31 have been added to claim further features. Applicants respectfully submit that these claims are allowable over the prior art relied upon by the Examiner, not only

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because they depend from allowable base claims, but also because each of these claims recites a unique combination of features not taught or suggested in the cited art.

Applicants have also added new Claim 32, which recites many of the features discussed above, which Applicants respectfully submit are not taught or suggested by Foley, alone or in combination with the cited art. Accordingly, in view of the discussion above, Applicants respectfully submit that new Claim 32 is in condition for allowance.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney in order to resolve such issues promptly.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and Applicants respectfully request that a Notice of Allowance be issued at the earliest opportunity.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.


Appl. No. : 10/658,736
Filed : September 9, 2003

Respectfully submitted,

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